UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,247	07/13/2000	Michael Zasloff	036870-5062-01	5537

9629 7590 02/24/2005

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,247	ZASLOFF ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/24/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation in part of 08/857288 now patented 6,143,738 which claims priority from Provisional Applications 60017627 and 60029541.

However, the parent case 08/857288 now patented 6,143,738 which claims priority from Provisional Applications 60017627 and 60029541 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant claims 1, 4-6 and 12-13 of this application as to methods for treating serum cholesterol, atherosclerosis, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal, since the parent case merely discloses a method for treating diabetes and/or obesity in a mammal.

Therefore, the filing date of the instant claims as to methods for treating serum cholesterol, atherosclerosis, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal, is deemed to be the filing date of the instant application, July 14, 2000, whereas the effective filing date of claim 1 as to methods for treating diabetes and/or obesity in a mammal is seen to be the filing date of the 08/857288 (6,143,738) which claims priority from Provisional Applications 60017627 and 60029541.

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and whether said art occurred more than one year prior to said priority date. Applicant will note that the art rejections are under both 35 U.S.C. § 102(a) and 102(b) because the priority date of the instant claims is in question.

Note that claims 2-3 and 7-11 are cancelled as Applicant states in the "Request to convert a provisional application to a nonprovisional application under 37 CFR 1.53(c)(3)" submitted July 13, 2001.

Currently, claims 1, 4-6 and 12-13 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 5 and 12 drawn to a method of reducing blood cholesterol levels in a mammal administering the compound herein, and the species of compound 1436 (depicted in Figure 1), submitted October 29, 2004 is acknowledged.

On consideration by the examiner, the Restriction Requirement dated September 3, 2004, is **withdrawn**.

The claims 1, 4-6 and 12-13 are examined on the merits herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,143,738.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for suppressing appetite in a mammal or inhibiting weight gain in a mammal comprising administering the same compound as instantly claimed.

The claim of the instant application is drawn to the method for treating obesity or diabetes in a mammal. It is well known that, in the obese individual who may also suffers diabetes, suppressing appetite or inhibiting weight gain is integral to the successful treatment of obesity or diabetes.

Thus, the instant claim 1 is seen to be anticipated by the claims 1-16 of U.S. Patent No. 6,143,738.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "administering ...." but missing " to a mammal or human in need thereof treatment" in the claims renders these claims indefinite. Thus, the method is unclear as to administering to whom for the treatment herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zasloff et al. (5,792,635, PTO-892).

Zasloff et al. discloses that administering the instant compound, compound 1436 (see its structure at col.9-10, 115-116, 159) with a pharmaceutically acceptable carrier (see col.4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col.1 line 63-65; col.2 line 21-22). Thus, Zasloff's method treats atherosclerosis in a mammal since atherosclerosis is a known generic term for diseases including cardiac infarction, angina

pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal (see the Merck Manual of Diagnosis and Therapy,17th ED, page 1654-1656).

Therefore, Zasloff et al. anticipates Claims 1, 4, and 6.

Claims 1, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zasloff et al. (5,842,740, PTO-892).

Zasloff et al. discloses that administering the instant compound, compound 412 (see its structure at col.41-42) and compound 1436 (see col. 9-10) with a pharmaceutically acceptable carrier (see col.4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col.1 line 63-65; col.2 line 21-22). Thus, Zasloff's method treats atherosclerosis in a mammal since atherosclerosis is a known generic term for diseases including cardiac infarction, angina pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal (see the Merck Manual of Diagnosis and Therapy,17th ED, page 1654-1656).

Therefore, Zasloff et al. anticipates Claims 1, 4, and 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zasloff et al. (5,792,635) or Zasloff et al. (5,842,740) in view of the Merck Manual of Diagnosis and Therapy (17th ED).

The same disclosure of Zasloff et al. in 5,792,635 or 5,842,740 has been discussed in the 102(b) rejection set forth above.

Zasloff et al. do not expressly disclose the employment of the compound therein in a method of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal.

The Merck Manual of Diagnosis and Therapy teaches that elevated serum cholesterol, hypertension diabetes mellitus, and obesity are the major risk factors for atherosclerosis (see page 1656 both left and right column entitled by "Risk Factors" and subtitles "Hypertension", "Diabetes mellitus" and "obesity").

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Zasloff et al., in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compound of Zasloff et al., in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol

levels in a mammal, since the prior art compounds are known to be used in treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal. Moreover, elevated serum cholesterol, hypertension, diabetes mellitus, and obesity are well known major risk factors for atherosclerosis and associated with atherosclerosis according to The Merck Manual of Diagnosis and Therapy.

Therefore, one of ordinary skill in the art would have reasonably expected that the prior art compounds, would have beneficial therapeutic effects and usefulness in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal by treating atherosclerosis or cardiac infarction, angina pectoris, or ischemic disorders of the heart, or ateriosclerotic diseases, or diabetic composition or diabetes, or hypertension in patents suffering therefrom.

Moreover, the patient population for atherosclerosis or cardiac infarction, angina pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension, is reasonably interpreted to encompass or overlap or coincide those patients suffering elevated serum cholesterol as claimed herein.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
February 14, 2005